

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

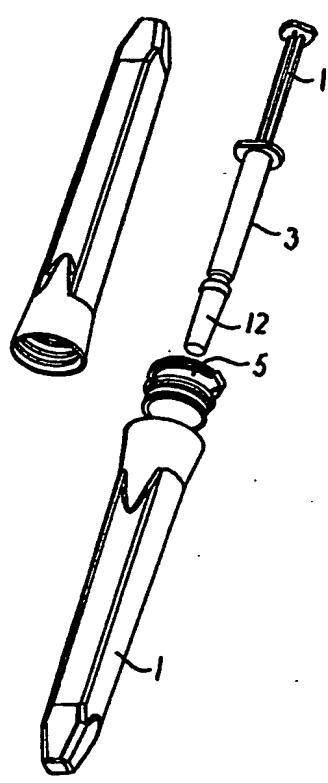
- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/00 // A61J 1/18, B65D 41/32, 101/00	A3	(11) International Publication Number: WO 99/26680 (43) International Publication Date: 3 June 1999 (03.06.99)
(21) International Application Number: PCT/DK98/00503 (22) International Filing Date: 19 November 1998 (19.11.98) (30) Priority Data: 01329/97 20 November 1997 (20.11.97) DK (71) Applicant (for all designated States except US): LEO PHARMACEUTICAL PRODUCTS LTD. A/S (LØVENS KEMISKE FABRIK PRODUKTIONS-AKTIESELSKAB) [DK/DK]; Industriparken 55, DK-2750 Ballerup (DK). (72) Inventors; and (75) Inventors/Applicants (for US only): LUND, Carsten [DK/DK]; Vinkelvej 11, DK-4760 Vordingborg (DK). HANSEN, Erik, Torngaard [DK/DK]; Gærdesmuttevej 29, DK-3390 Hundested (DK). (74) Agent: HOFMAN-BANG & BOUTARD, LEHMANN & REE A/S; Hans Bekkevolds Allé 7, DK-2900 Hellerup (DK).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>In English translation (filed in Danish).</i> (88) Date of publication of the international search report: 15 July 1999 (15.07.99)
(54) Title: A CONTAINER FOR A HYPODERMIC SYRINGE (57) Abstract <p>A container (1) for a hypodermic syringe (3) and of the type which allows it to be seen or observed in another manner that the container has been opened. The container (1) comprises a plug (5) having more than one tamper-proof mechanism. This ensures both that the hypodermic syringe (3) can reach the user in a state which allows it to be seen whether it has been opened, and that, after use, it can be disposed of in such a state that re-use is impeded considerably.</p> 		

A container for a hypodermic syringe

The invention relates to a container for a hypodermic syringe of the type defined in the introductory portion of
5 the main claim.

Hypodermic syringes are used both in medical environments (hospitals, health care centres, etc.) and in the field (at home, accidents, in the open, etc.) It is essential
10 in both situations to ensure cleanliness and an indication as to whether the hypodermic syringe has been used before. This has manifested itself in a wish for several levels of safety mechanisms, also called tamper-proof or tamper-evident mechanisms. There is also a wish on the
15 part of the users for simple disposal after use of the hypodermic syringe. This results in so-called waste management initiatives from the manufacturers.

Separate blister packaging of syringes and needles is
20 known, where the parts must first be assembled, injection liquid must be taken from an ampoule, and the parts must be separated after use. Various types are available from e.g. Becton Dickinson, Sanosafe and Owen Mansfort. It is also known to use rigid packages.

25

Accordingly, the object of the invention is to provide a container for a hypodermic syringe which may be supplied to the user as an assembled whole, and which may be disposed of as an assembled whole by the user after use. Before use, the assembled whole comprises hypodermic syringe with needle, injection liquid, container, plug and
30 closure. After use, the injection liquid has been injected and the hypodermic syringe is totally or partly empty and may have been rendered unusable. The needle
35 need not be bent, broken or be made unusable in another possibly hazardous manner.

According to the invention, the container for a hypodermic syringe of the type which allows it to be seen or observed in another manner that the container has been opened, is characterized in that the container comprises a plug having more than one tamper-proof mechanism. This ensures that the container for a hypodermic syringe may be supplied to the user as an assembled whole and be disposed of as an assembled whole by the user after use, it being ensured that the container has not been opened before it is to be used, and that later attempts at use are rendered difficult.

According to the invention, the container for a hypodermic syringe may be characterized in that the plug includes both a full or divided film connection and a plurality of flaps, each of which constitutes a tamper-proof mechanism. At least two mutually independent mechanisms are obtained hereby.

It has been found particularly expedient in the container for a hypodermic syringe that the plug includes an annular film connection and two flaps.

According to the invention, the container for a hypodermic syringe may be supplied to the user with the hypodermic syringe with injection liquid and needle ready for use. This provides a disposable injection system which is easy to use and dispose of by the user.

Moreover, it has been found expedient that the plug is provided with a plurality of film hinges, a plurality of film connections, a plurality of projections and a plurality of knobs. It is hereby possible to form several different tamper-proof mechanisms.

When two film hinges are provided between the body of the plug and the lid formed by separation at the film connections by opening of the container, and projections are provided between the film hinges and are capable of being engaged with recesses in the body of the plug, and knobs are provided at the film hinges and engage the body of the plug only when the projections are in engagement with the recesses, a particularly expedient embodiment of the container according to the invention is achieved.

10

The invention will be explained below with reference to the drawing, in which

fig. 1 shows a container seen in a three-rectangular view,

15

fig. 2 shows the container with plug and hypodermic syringe seen in perspective, said parts being pulled apart,

fig. 3 shows the plug in detail in a three-rectangular view and in perspective,

20

fig. 4 shows the container and the hypodermic syringe seen in section in two mutually perpendicular and centrally positioned planes,

25

fig. 5 shows a package with the container with hypodermic syringe partly in section,

fig. 6 shows the package in perspective,

30

fig. 7 shows another embodiment of the container,

fig. 8 shows another embodiment of the plug, and

35

fig. 9 shows the plug in section, with the lid pressed down.

Fig. 1 shows the container 1 in which a hypodermic syringe generally designated by 3 (see fig. 2) may be arranged. The container 1 is shown in fig. 1 in a three-rectangular view. The container 1 is made as an injection-moulded article of polypropylene. By suitable selection of parameters, polypropylene may give articles which are almost transparent, thereby allowing it to be seen whether there is something in the hypodermic syringe 3, and an optional label or print on the hypodermic syringe 3. The container shown in fig. 1 is edged so as to be a tight fit in the package 7 (see fig. 6).

15

Fig. 2 shows the container 1, the hypodermic syringe 3 and the plug 5 which is used for closing the container 1. When the hypodermic syringe 3 is packed, the injection liquid is filled in a known manner into the hypodermic syringe 3, a piston 11 is inserted, and a needle (not shown) is covered by a needle case 12. The hypodermic syringe 3 is then placed in the container 1, and the plug 5 is applied.

20

Fig. 3 shows the plug 5 both in a three-rectangular view and in perspective. The plug 5 is injection-moulded of polyethylene, which, by suitable selection of parameters and colour, may be given properties that enable pilfer-proof, tamper-proof and tamper-evident properties. There is thus a film connection at 6, which may be injection-moulded such that it may be broken without difficulty, and when it has been broken, it is easy to see that the container 1 has been opened. After use of the hypodermic syringe 3, it is moved down through the plug 5 into the container 1. The lid 9, which is formed by opening the plug 5 along the film connection 6, and which may tilt

30

35

along the hinge 10, is then pressed so far down into the plug 5 that the flaps 16 and 17 hold the lid 9 in a position which does not readily allow re-opening of the container 1.

5

Fig. 4 is a sectional view of the hypodermic syringe 3 in the container 1. The hypodermic syringe 3 is unused, and the lid 9 is not removed from the plug 5 by rupture along the film connection 6. The needle case 12 is positioned
10 over the needle (not shown). After opening of the container 1 the needle case 12 may be put back into the container 1, since the piston, after use, is pressed completely or partly down, thereby making room in the container 1 so that the needle need not be positioned in the
15 needle case 12. This reduces the risk of e.g. the user getting unintentionally pricked by the needle.

Fig. 5 shows a plurality of containers 1 juxtaposed in a package 7. When the container 1 is suitably shaped,
20 stacking possibility before the hypodermic syringe 3 is placed in the container 1 and the plug 5 is applied as well as a small packing volume in the package 7 may be achieved.

25 Fig. 6 shows a plurality of containers 1 with plugs 5 positioned in a package 7.

In a particular embodiment of the invention in which the container 1 with plug 5 is used for storing the hypodermic
30 mic needle 3 when this is not in use, the plug 5 is constructed in the manner described below with reference to fig. 8.

In fig. 8, the plug 5 is provided with two hinges 10 for
35 the connection between the lid 9 and the part of the plug 5 which forms the engagement with the container 1. This

part of the plug 5 is called the plug body 25 below. When the plug body 25 and the lid 9 are connected with more than one hinge (see fig. 8) constructed as a film hinge, it is ensured that the lid 9 is controlled better, so that it is more difficult to work open when the hypodermic syringe has been used and again been arranged in the container 1. In this embodiment, the number of film connections 16 which are broken when the lid 9 is opened, is six, arranged such that there are three on each side of the film hinges 10. In the embodiment shown, both film hinges 10 and film connections 26 are discrete, which means that they are separated from each other so that their mutual position and number may be determined. However, the number and position are not as essential as the function, it being important that the lid may be controlled, and that it is clear to the user whether the container 1 has been opened before. A boss 28 is provided between the hinges 10 shown in this embodiment, said boss 28 being capable of cooperating with the plug body 25 in a radial direction when the lid 9, after completed use of the hypodermic syringe, is pressed down in the plug body 25. Moreover, a second boss 29 or projection is provided in a diametrical position with respect to the previously mentioned boss 28, said second boss 29 serving as a finger grip when the lid 9 is opened. This finger grip cooperates with a groove 31 in the plug body 25 when the lid 9 is pressed down in the body 25 after use. When the finger grip cooperates with the groove 31, the lid 9 is locked, thereby making it difficult to re-open the container 1. The number and the position of radially positioned bosses 28, projections 29 and finger grip are not more essential than their function.

Two knobs 33 are arranged on the lid 9 in an axial direction near the hinges 10. These knobs 33 are to make re-opening of the lid 9 additionally difficult. The number

and position of the knobs 33 are likewise less essential as long as the function is achieved.

5 The lid 9 itself is not necessarily round or circular. It may be oval or elliptic so that the hole in the plug is filled as best as possible when the lid 9 is pressed down in the plug after use. It is almost oval in fig. 8. The underside of the lid may be provided with various ribs or grooves which can inter alia contribute to controlling
10 the hypodermic syringe when it is in the container.

The container itself may be formed with a writing field 37 (see fig. 7) which has been obtained by spark machining or sand blasting in the mould. Notes on the individual
15 treatment may be written in this writing field 37.

Fig. 9 shows a plug 5 in section. The lid 9 is shown in two positions, one before use of the hypodermic syringe, the other after use of the hypodermic syringe. After use
20 of the hypodermic syringe, it is placed in the container and the lid 9 is pressed down in the plug body 25 so that flaps 16 or 29 engage the body 25.

The invention is not restricted to the above-mentioned
25 embodiments, but may be modified by a skilled person in many ways within the scope of the claims. Thus, the hypodermic syringe should be adapted to the container if it is desired to achieve the greatest amount of safety. The selection of material is not critical, as long as the
30 functional requirements are satisfied. It is thus expedient to use ethylene for the plug, since this gives some good breaking properties. On the other hand, it is expedient to use polypropylene for the container, as this gives a solid, dimensionally stable container which may
35 be made almost transparent by injection moulding. There may be one or more flaps, and the film connection may be

divided into segments. The injection liquid need not be a liquid proper, it must merely be in a form that may be passed from a hypodermic syringe through a needle-like device into a body. The injection liquid may thus be a
5 powder.

P a t e n t C l a i m s :

1. A container (1) for a hypodermic syringe (3) and of
5 the type which allows it to be seen or observed in an-
other manner that the container has been opened,
c h a r a c t e r i z e d in that the container (1) com-
prises a plug (5) having more than one tamper-proof
mechanism.
- 10 2. A container (1) for a hypodermic syringe (3) accord-
ing to claim 1, c h a r a c t e r i z e d in that the
plug (5) includes both a full or divided film connection
(6) and a plurality of flaps (16, 17, 28, 29), each of
15 which constitutes a tamper-proof mechanism.
3. A container (1) for a hypodermic syringe (3) accord-
ing to claim 1 or 2, c h a r a c t e r i z e d in that
the plug (5) includes an annular film connection (6) and
20 two flaps (16, 17).
4. A container (1) for a hypodermic syringe (3) accord-
ing to one or more of claims 1-3, c h a r a c t e r -
i z e d in that it is supplied to the user with the hy-
25 podermic syringe (3) with injection liquid and needle
ready for use.
5. A container (1) for a hypodermic syringe (3) accord-
ing to one or more of claims 1-4, c h a r a c t e r -
30 i z e d in that the plug (5) is provided with a plural-
ity of film hinges (10), a plurality of film connections
(26), a plurality of projections (28, 29) and a plurality
of knobs (33).
- 35 6. A container (1) for a hypodermic syringe (3) accord-
ing to one or more of claims 1-5, c h a r a c t e r -

i z e d in that two film hinges (10) are provided between the body (25) of the plug (5) and the lid (9) which is formed by separation at the film connections (26) by opening of the container (1), that projections (28, 29) are provided between the film hinges (10) and are capable of being engaged with recesses (31) in the body (25) of the plug, and that knobs (33) are provided at the film hinges (10) and engage the body (25) of the plug only when the projections (28, 29) are in engagement with the recesses (31).

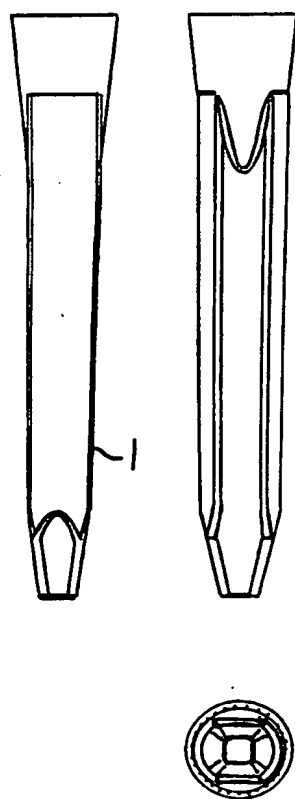


FIG. 1

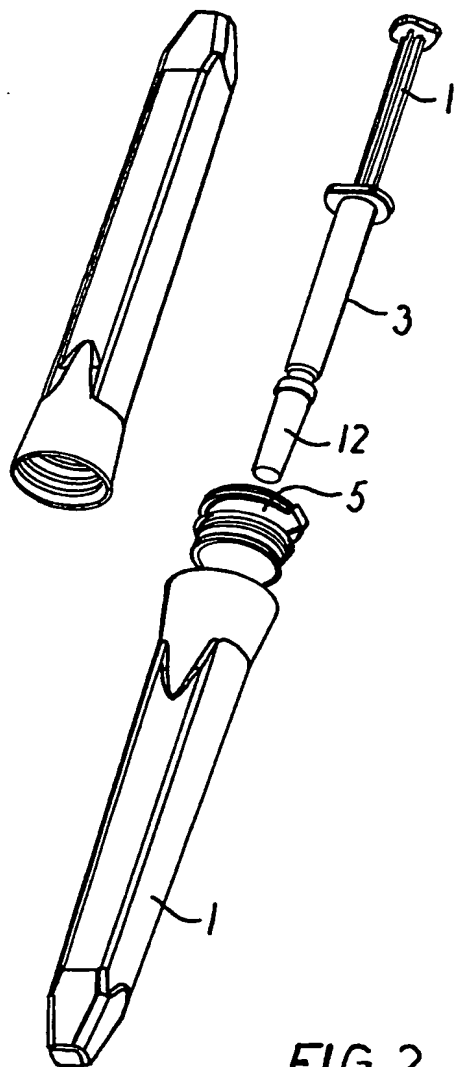


FIG. 2

2/5

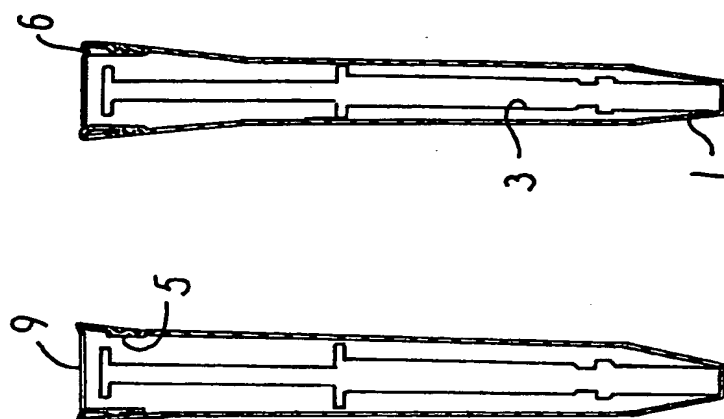


FIG. 4

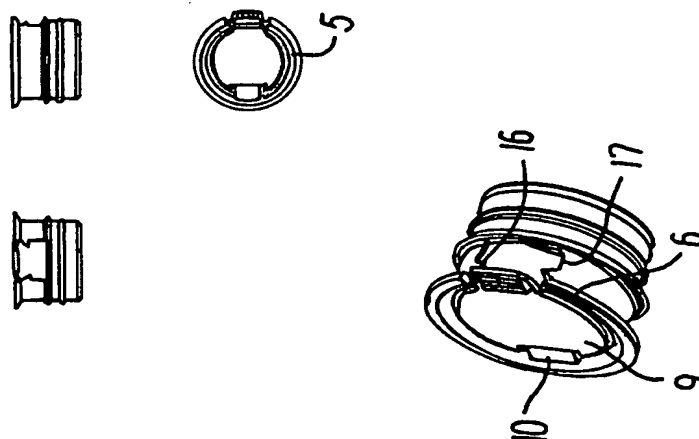


FIG. 3

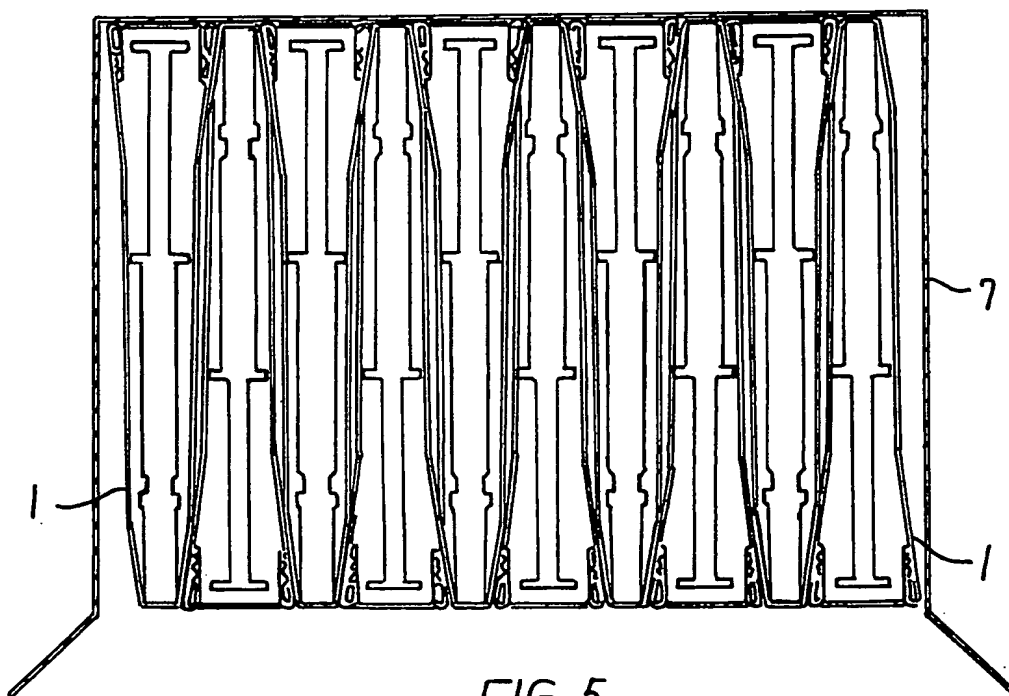
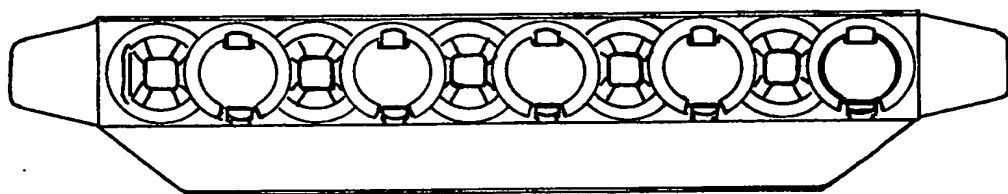


FIG. 5

4/5

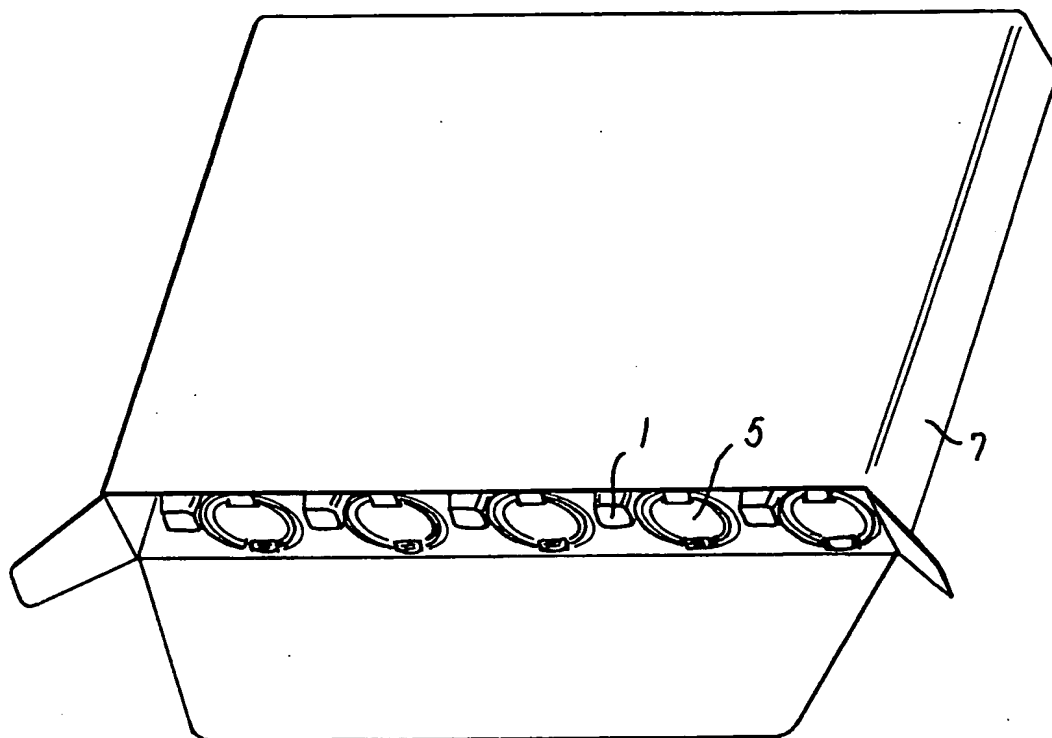


FIG. 6

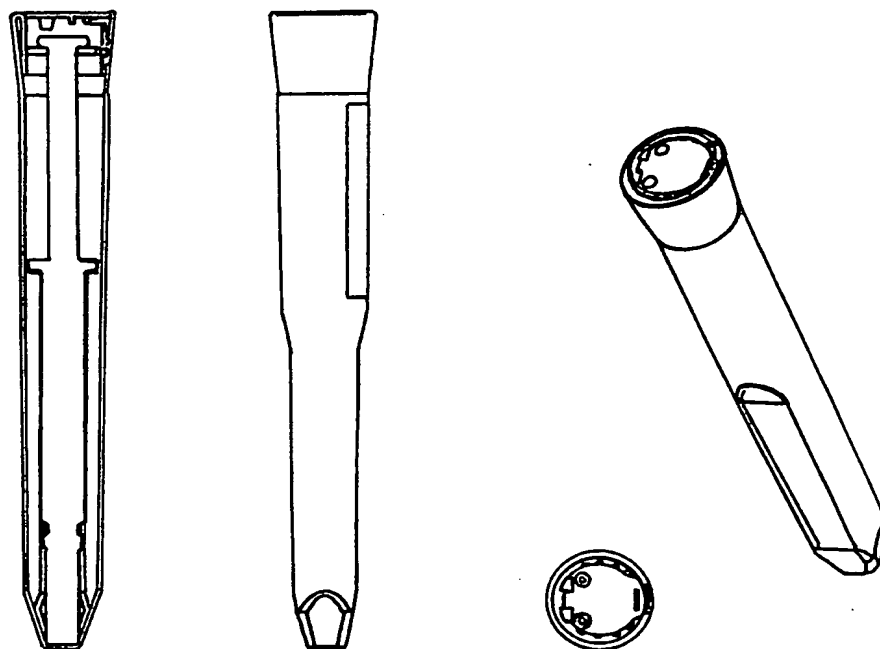


FIG. 7

5/5

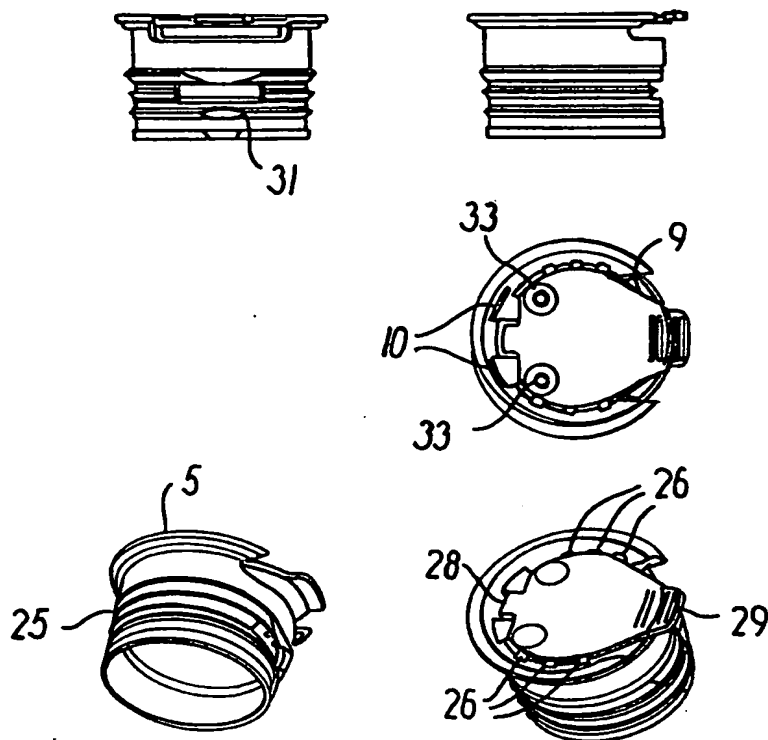


FIG. 8

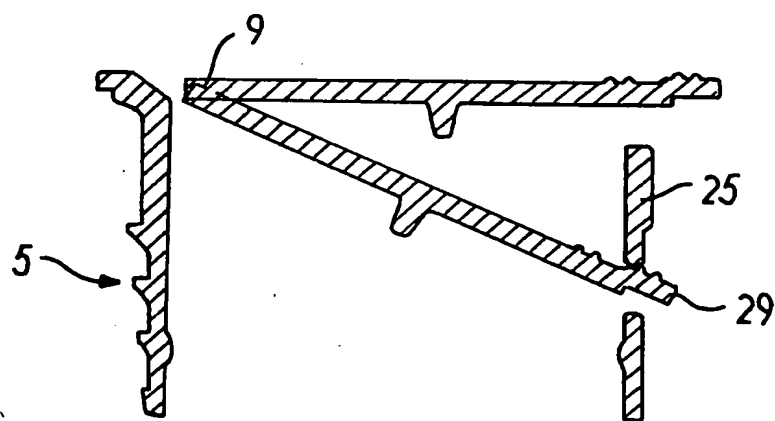


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 98/00503

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/00 // A61J1/18, B65D 41/32, B65D 101/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M, A61J, B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4886497 A (C.SCHOLL,JR.), 12 December 1989 (12.12.89), column 2, line 54 - column 3, line 14; column 5, line 52 - line 60	1,4
A	--	2-3,5-6
X	WO 9420380 A1 (PORTOLA PACKAGING,INC.), 15 Sept 1994 (15.09.94), abstract	1
A	--	2-6
A	US 3008570 A (Z.M.ROEHR ET AL), 14 November 1961 (14.11.61), see the whole document	1-6
	--	

☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

- * Special categories of cited documents
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

6 May 1999

Date of mailing of the international search report

14 -05- 1999

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer

Lars Jakobsson / itw
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00503

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4402418 A (E.M.OSTROWSKY), 6 Sept 1983 (06.09.83), abstract --	1-6
A	US 4479586 A (E.J.CSASZAR), 30 October 1984 (30.10.84), abstract -- -----	1-6

INTERNATIONAL SEARCH REPORT
Information on patent family members

07/04/99

International application No.
PCT/DK 98/00503

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
US	4886497	A	12/12/89	US 5158550 A	27/10/92
WO	9420380	A1	15/09/94	AU 6402794 A	26/09/94
				CA 2157398 A	15/09/94
				GB 2290782 A,B	10/01/96
				GB 2305167 A,B	02/04/97
				GB 2312423 A,B	29/10/97
				GB 9517979 D	00/00/00
				GB 9621311 D	00/00/00
				GB 9719294 D	00/00/00
				US 5456376 A	10/10/95
				US 5593055 A	14/01/97
				US 5630520 A	20/05/97
				US 5687866 A	18/11/97
				US 5755348 A	26/05/98
US	3008570	A	14/11/61	NONE	
US	4402418	A	06/09/83	NONE	
US	4479586	A	30/10/84	AU 554167 B	07/08/86
				AU 1496783 A	08/12/83
				BE 896917 A	01/12/83
				CA 1216548 A	13/01/87
				DE 3319709 A	01/12/83
				FR 2527558 A,B	02/12/83
				GB 2121392 A,B	21/12/83
				JP 59037150 A	29/02/84
				NL 8301945 A	02/01/84
				SE 457076 B,C	28/11/88
				SE 8303036 A	02/12/83
				US 4461390 A	24/07/84
				CA 1247558 A	27/12/88